Complete Summary

GUIDELINE TITLE

Tests of glycemia in diabetes.

BIBLIOGRAPHIC SOURCE(S)

Goldstein DE, Little RR, Lorenz RA, Malone JI, Nathan DM, Peterson CM. Tests of glycemia in diabetes. Diabetes Care 2004 Jan;27(Suppl 1):S91-3. [6 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Type 1 diabetes mellitus
- Type 2 diabetes mellitus

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Endocrinology
Family Practice
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses

Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To summarize current knowledge about the tests used most widely in monitoring the glycemic status of people with diabetes, addressing both patient- and physician/laboratory-based testing

TARGET POPULATION

Adults with diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

1. Self-monitoring of blood glucose by patients
2. Blood glucose testing by health care providers (e.g., laboratory glucose or finger-stick glucose)
3. Urine and blood glucose and ketone testing
4. Glycated hemoglobin (GHb, also referred to as glycohemoglobin, glycosylated hemoglobin, HbA_{1c}, or HbA_1) testing; glycated serum protein testing, including fructosamine

MAJOR OUTCOMES CONSIDERED

- Short-term glycemic control as reflected by individualized blood glucose targets
- Long-term glycemic control as reflected in glycated hemoglobin target (<7%)
- Risk of the development and progression of chronic complications of diabetes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This paper was peer-reviewed, modified, and approved by the Professional Practice Committee and the Executive Committee of the Board of Directors. The paper was most recently reviewed and revised in 2000.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Blood Glucose Testing by Patients

1. Based principally on the Diabetes Control and Complications Trial (DCCT) results, it is recommended that most individuals with diabetes should attempt to achieve and maintain blood glucose levels as close to normal as is safely

possible. Because most patients with type 1 diabetes can achieve this goal only by using self-monitoring of blood glucose (SMBG), all treatment programs should encourage SMBG for routine daily monitoring. Daily SMBG is especially important for patients treated with insulin or sulfonylureas to monitor for and prevent asymptomatic hypoglycemia. Frequency and timing of glucose monitoring should be dictated by the needs and goals of the individual patient, but for most patients with type 1 diabetes, SMBG is recommended three or four times daily. The optimal frequency of SMBG for patients with type 2 diabetes is not known, but should be sufficient to facilitate reaching glucose goals. When adding to or modifying therapy, type 1 and type 2 diabetic patients should test more often than usual. The role of SMBG in stable, diet-treated patients with type 2 diabetes is not known.

2. Self-monitoring of blood glucose is recommended for all insulin-treated patients with diabetes. Self-monitoring of blood glucose may be desirable in patients treated with sulfonylureas or other insulin secretagogues and in all patients not achieving glycemic goals. Data indicate that only a minority of patients perform SMBG. Efforts should be made to substantially increase appropriate use of SMBG. Barriers to increasing use of SMBG include cost of testing, inadequate understanding by both health care providers and patients about the health benefits and proper use of SMBG results, patient psychological and physical discomfort associated with finger-prick blood sampling, and inconvenience of testing in terms of time requirements, physical setting, and complexity of the technique.

   Given the importance of SMBG to diabetes care, government, third-party payers, and others should strive to make the procedure readily accessible and affordable for all patients who require it. Thus, self-monitoring of blood glucose should be an important component of any health care benefits package.

3. Because the accuracy of SMBG is instrument and user dependent, it is important for health care providers to evaluate each patient's monitoring technique, both initially and at regular intervals thereafter. Use of calibration and control solutions on a regular basis by patients helps assure accuracy of results. In addition, because laboratory methods measure plasma glucose, many blood glucose monitors approved for home use and some test strips now calibrate blood glucose readings to plasma values. Plasma glucose values are 10 to 15% higher than whole blood glucose values, and it is crucial that people with diabetes know whether their monitor and strips provide whole blood or plasma results.
4. Optimal use of SMBG requires proper interpretation of the data. Patients should be taught how to use the data to adjust medical nutrition therapy (MNT), exercise, or pharmacological therapy to achieve specific glycemic goals. Health professionals should evaluate at regular intervals the patient's ability to use SMBG data to guide treatment. Although a number of SMBG methods store test results and with a computer interface can provide sophisticated analyses of blood glucose data, it is not known whether use of these data management systems yields better glucose control than patient review of results recorded in a logbook.

1. Blood glucose testing (e.g., laboratory glucose or finger-stick glucose) should be available to providers for use as needed. With the availability of SMBG and glycated protein testing, routine laboratory blood glucose testing by health care providers should no longer be used to assess glycemic control except to supplement information obtained from other testing methods and to test the accuracy of SMBG. When adjusting oral glucose-lowering medication(s) in a patient not taking insulin, laboratory testing also may be appropriate.
2. Comparisons between results from patient self-testing of blood glucose in the clinic and simultaneous laboratory testing are useful to assess the accuracy of patient results. If such testing is performed by health care providers using portable capillary blood testing devices rather than standard hospital or clinic laboratory methods, rigorous quality control procedures should be used. Participation in the College of American Pathologists voluntary proficiency testing program for home-use testing devices is recommended.
3. Continuous ambulatory blood glucose monitoring may be used to determine 24-hour blood glucose patterns and to detect unrecognized hypoglycemia; however, its role in improving diabetes outcomes remains to be established.

Urine Glucose Testing

1. Self-monitoring of blood glucose has supplanted urine glucose testing for most patients.
2. If patients choose to perform urine glucose testing, they should fully understand the test limitations. Specifically, patients should be taught that although urine glucose measurements correlate with blood glucose measurements, urine glucose testing provides only a rough estimate of prevailing blood glucose levels. Patients should be taught that urine glucose testing provides no information about blood glucose levels below the renal threshold, which for most patients is 180 mg/dL (10 mmol/L).

Urine/Blood Ketone Testing

1. Ketone testing is important part of monitoring in type I diabetic patients, in pregnancy with pre-existing diabetes, and in gestational diabetes. The presence of ketones may indicate impending or even established ketoacidosis, a condition that requires immediate medical attention.
2. All people with diabetes should test for ketones during acute illness or stress or when blood glucose levels are consistently elevated (e.g., >300 mg/dL [>16.7 mmol/L]), during pregnancy, or when any symptoms of ketoacidosis, such as nausea, vomiting, or abdominal pain, are present.
3. Ketone testing materials should be available in the office/clinic setting. Health care professionals should be aware, however, that currently available urine ketone tests are not reliable for diagnosing or monitoring treatment of ketoacidosis. Blood ketone testing methods that quantify beta-hydroxybutyric acid, the predominant ketone body, are available and are preferred over urine ketone testing for diagnosing and monitoring ketoacidosis. Home tests for beta-hydroxybutyric acid are available.

Glycated Protein Testing

Glycated Hemoglobin Testing

1. Glycated hemoglobin (HbA1c) has become the preferred standard for assessing glycemic control.
2. The glycated hemoglobin test (A1C) has been shown to predict the risk for the development of many of the chronic complications in diabetes; however, optimal use of glycated hemoglobin testing for this purpose requires the standardization of glycated hemoglobin assays. Without standardization, reported results between laboratories may not be comparable, even if both laboratories use the same assay method. It is desirable that laboratories use only glycated hemoglobin assay methods that have passed certification testing by the National Glycohemoglobin Standardization Program, indicating that the results are traceable to the Diabetes Control and Complications Trial reference method. It is also desirable that all laboratories performing glycated hemoglobin testing participate in the College of American Pathologists proficiency testing survey for glycated hemoglobin started in mid-1996, which uses whole-blood specimens. Regardless of the assay method type and specific analyte qualified, all results should be reported as "% HbA_{1c}" or "% HbA_{1c} equivalents."
3. Glycated hemoglobin testing should be performed routinely in all patients with diabetes, first to document the degree of glycemic control at initial assessment, then as part of continuing care. Since glycated hemoglobin reflects a mean glycemia over the preceding 2 to 3 months, measurement approximately every 3 months is required to determine whether a patient's metabolic control has reached and been maintained within the target range. For any individual patient, the frequency of glycated hemoglobin testing should be dependent on the treatment regimen used and on the judgment of the clinician. In the absence of well-controlled studies that suggest a definite testing protocol, expert opinion recommends glycated hemoglobin testing at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control) and more frequently (quarterly assessment) in patients whose therapy has changed or who are not meeting glycemic goals.

   The American Diabetes Association recommends that the goal of therapy should be a glycated hemoglobin of <7% and that physicians should reevaluate and, in most cases, significantly change the treatment regimen in patients with glycated hemoglobin values consistently >8%. (These specific glycated hemoglobin values apply only to assay methods that are certified as traceable to the Diabetes Control and Complications Trial reference method.)

Glycated Serum Protein

1. In situations where the A1C test cannot be measured or may not be useful (e.g., hemolytic anemias), the glycated serum protein (GSP) assay (e.g., fructosamine assay) may be of value in the assessment of the treatment regimen.

   A single measurement of GSP provides an index of glycemic status over the preceding 1 to 2 weeks, while a single A1C test provides an index of glycemic status over a considerably longer period of time, 2 to 3 months.

2. Simultaneous measurements of GSP and the A1C test might complement one another and provide more useful clinical information than the A1C test alone.

However, additional studies are needed to confirm the clinical utility of this approach.

3. Measurement of GSP, regardless of the specific assay method, should not be considered equivalent to the A1C test, since it only indicates glycemic control over a short period of time. Therefore, GSP assays would have to be performed on a monthly basis to gather the same information as measured by the A1C test three to four times a year. Unlike the A1C test, GSP has not yet been shown to be related to the risk of the development or progression of chronic complications of diabetes.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Recognition of barriers to the use of self-monitoring of blood glucose (SMBG): (1) high costs of SMBG, (2) inadequate education of both health care providers and patients about the health benefits and proper use of SMBG testing results, (3) patient psychological and physical discomfort associated with finger-prick blood sampling, and (4) patient-perceived inconvenience of testing in terms of time requirements and complexity of the technique
- Greater success at increasing both the frequency with which patients perform SMBG and the optimal use of the data to improve glycemic control
- Increased achievement of individualized glycemic targets
- Increased understanding and appropriate utilization of the following laboratory parameters in the clinical evaluation and treatment of diabetes: urine ketones, glycated hemoglobin, glycated serum protein, and glycated serum albumin

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This position statement does not address tests for diabetes screening and diagnosis.

- The optimal frequency of self-monitoring of blood glucose for patients with type 2 diabetes is not known, but should be sufficient to facilitate reaching glucose goals.
- The role of self-monitoring of blood glucose in stable, diet-treated patients with type 2 diabetes is not known.
- Although a number of self-monitoring of blood glucose methods store test results and with a computer interface can provide sophisticated analyses of blood glucose data, it is not known whether use of these data management systems yields better glucose control than patient review of results recorded in a logbook.
- Unlike glycated hemoglobin, glycated serum protein has not yet been shown to be related to the risk of the development or progression of chronic complications of diabetes.
- Although continuous ambulatory blood glucose monitoring may be used to determine 24-hour blood glucose patterns and to detect unrecognized hypoglycemia, its role in improving diabetes outcomes remains to be established.
- Evidence is only one component of decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances such as comorbid and coexisting diseases, age, education, disability, and above all, patient's values and preferences must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies such as the one adapted by the American Diabetes Association may miss some nuances that are important in diabetes care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Goldstein DE, Little RR, Lorenz RA, Malone JI, Nathan DM, Peterson CM. Tests of glycemia in diabetes. Diabetes Care 2004 Jan;27(Suppl 1):S91-3. [6 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 Nov (revised 2000; republished 2004 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

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GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors of Position Statement, Initial Draft: David E. Goldstein, MD, Chair; Randie R. Little, PhD; Rodney A. Lorenz, MD; John I. Malone, MD; David M. Nathan, MD; Charles M. Peterson, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

The guideline was originally approved in November 1996; the most recent review/revision was completed in 2000.

American Diabetes Association (ADA) position statements are reissued annually.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

The recommendations in this paper are based on the evidence reviewed in the following publication:

- Goldstein DE, Little RR, Lorenz RA, Malone JI, Nathan D, Peterson CM: Tests of glycemia in diabetes (Technical Review). Diabetes Care 1995;18:896-909.

Print copies: Available from the American Diabetes Association (ADA), 1701 North Beauregard Street, Alexandria, VA 22311.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 1, 1998. The information was verified by the guideline developer on December 15, 1998. This summary was updated by ECRI on April 1, 2001, March 14, 2002, April 21, 2003, and March 24, 2004.

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